

**REMARKS**

Applicants attorney would like to thank the examiner for careful consideration of this application.

Currently, claims 1-40 are pending in this application. Claims 22-40 have been withdrawn from consideration pursuant the restriction requirement of the Office Action mailed July 20, 2005. The claims of groups I and II, claims 1-8 and 17-21, respectively, have been rejoined with applicants elected group II, claims 9-16, and are marked "Original" in the above listing of claims.

**Rejections under 35 U.S.C. §102**

Claims 1-21 were rejected under 35 U.S.C. §102(a) as being anticipated by Hartgerink et al. (Science, 2001) and Hartgerink et al. (PNAS, 2002). It is respectfully submitted that the Hartgerink references are not "by another" as required by §102(a), and therefore are not prior art. A Katz declaration by Samuel I. Stupp designating that the above identified Hartgerink references are not by another is concurrently submitted herewith. Applicants further submit that these references published less than one (1) year prior to the filing date of the pending application and therefore would not be prior art under 35 U.S.C. §102(b). In light of the declaration submitted herewith, the Examiners rejections are rendered moot.

Claims 1-7 and 17-20 stand rejected under 35 USC 102(b) as being anticipated by U.S. Patent No. 6,096,863 to Fields et al. (hereinafter "Fields '863") or WO 98/07752 to Fields et al. (hereinafter "Fields '752").

Fields '863 and Fields '752 describe a self assembling peptide-amphiphile with a lipophilic portion and peptide portion wherein the peptide portion has secondary structure. The lipophilic portion of the peptide amphiphile must contain at least two (2) long alkyl groups, "The lipophilic portion can be any organic group having at least two long alkyl groups (preferably linear chains)..." (Fields '863 col 4, ln 37-38 and Fields '752 pg 6, ln17-18).

It is well established that in order for a prior art reference to anticipate a claim, the reference must disclose each and every element of the claim with sufficient clarity to prove its existence in prior art. The disclosure requirement under 35 USC 102 presupposes knowledge of one skilled in art of claimed invention, but such presumed knowledge does not grant license to

read into prior art reference teachings that are not there. See Motorola Inc. v. Interdigital Technology Corp., 43 USPQ2d 1481 (1997 CAFC).

As amended, independent claims 1 and 17 are directed to peptide amphiphiles that include a hydrophobic component and a hydrophilic component that are covalently bound, wherein the hydrophobic component comprises a single alkyl group. In contrast, the lipophilic component of Fields '836 and Fields '752 contains "at least two" alkyl groups. Neither Fields '836 or Fields '752 describe or suggest a peptide amphiphile in which the hydrophobic component has only one alkyl group, and therefore, fail to describe each and every element of the present claimed invention. As such, the rejection of claims 1-21 should be withdrawn.

Claims 2-7 and 18-20, depend from and add further limitation to amended independent claims 1 and 17 and are deemed allowable for at least the same reasons in connection with amended independent claims 1 and 17. Reconsideration is respectfully requested.

### **Rejections under 35 U.S.C. §103**

Claims 1-21 were rejected under 35 U.S.C. §103(a) as being unpatentable over Fields '863 in view of Murata et al. (J Biol Chem, 1991) (hereinafter "Murata").

As discussed above, Fields '863 describes a peptide-amphiphile with a lipophilic component containing at least two alkyl groups. The amphiphilic peptides of Murata consist solely of amino acids and do not contain alkyl groups. The amphiphilicity of the peptides described in Murata arises from the use of hydrophobic and hydrophilic amino acids. Self assembly of these peptides occurs through interactions between amino acids.

"To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (Fed. Cir. 1974)". Applicants also respectfully submit that "in order to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success. Finally, the prior art references must teach or suggest all the claims limitations. The teachings or suggestions to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicants'

disclosure.” See MPEP § 2142, citing In re Vaeck, 947 F.2d 488, 20 USPQ 2d. 1438 (Fed. Cir. 1991).

Amended independent claims 1 and 17 and independent claim 9 are directed to a peptide amphiphile with a hydrophobic component containing one alkyl group. Fields ‘863 fails to teach or suggest a peptide-amphiphile containing one alkyl group. Murata fails to teach or suggest a peptide amphiphile containing *any* alkyl groups and, consequently, fails to teach or suggest a peptide amphiphile having a single alkyl group. Thus, Murata fails to cure the deficiencies of Fields ‘863. Additionally, one skilled in the art would not be motivated by the teaching of Murata to modify the teaching of Fields to arrive at a peptide-amphiphile having one alkyl chain, and neither reference provides an expectation of successfully making a self assembling peptide-amphiphile with a single alkyl chain. In light to the foregoing, the cited references fail to render claims 1-21 and therefore the rejection should be withdrawn.

#### **Rejections under 35 USC 102 or 103**

Claims 1-21 stand rejected under 35 U.S.C. §102(b) as being anticipated by or, in the alternative, under 35 U.S.C. §103(a) as being obvious over Yamada et al. (Chem Letters, 1984) (hereinafter “Yamada”).

Yamada describes the preparation of a “Double-chain amphiphile with oligo-L-glutamic acid-head group” (pg 1713, ln 1) and their use to form highly ordered aggregates when placed in water.

The peptide amphiphiles of Yamada clearly contain two alkyl chains. Therefore, Yamada fails to describe or suggest a peptide amphiphile containing a single alkyl group and fails to disclose each and every limitation of amended independent claims 1 and 17 and independent claim 9. Furthermore, Yamada provides no motivation to one skilled in the art to modify the peptide-amphiphile by using one alkyl chain, and teaching of Yamada provides no reasonable expectation of successfully making a peptide-amphiphile with a single alkyl chain that self assembles. Consequently, Yamada fails to describe, teach or suggest each and every limitation of amended independent claims 1 and 17 and independent claim 9 and fails to anticipate or make obvious Applicants claimed invention.

Additionally, the peptide component of the peptide amphiphiles of Yamada are composed of a single amino acid, L-glutamic acid, and Yamada fails to provide any teaching or

suggestion that a peptide-amphiphile containing a peptide other than one composed solely of L-glutamic acid will allow self assembly. Therefore, one of ordinary skill in the art would not be motivated by the teaching of Yamada to arrive at the claimed invention nor would one skilled in the art expect to achieve self assembly as described by Yamada using an peptide-amphiphile with a peptide composed of amino acids other than L-glutamic acid.

Accordingly, Yamada fails to anticipate or render obvious amended independent claims 1 and 17 and independent claim 9, therefore this rejection should be withdrawn.

**CONCLUSION**

In view of the amendments and remarks presented herein, Applicants submit that pending claims 1-21 are in condition for final allowance and notice to such is respectfully requested.

This response has been timely filed when considered with the Petition for a two (2) month extension of time. In the event that an additional fee is required for this response, the Commissioner is hereby authorized to charge such fees to Deposit Account No. 50-0436.

Should the Examiner have any questions or comments, or need any additional information from Applicant's attorney, he is invited to contact the undersigned at his convenience.

Respectfully submitted,

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